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Reykjavík 23 May 2019
UST201903-094/H.I.I.
07.06.04

Authorisation for placing the biocidal product *Loppex* on the market in Iceland by mutual recognition

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of Loppex on 29th April 2016. The case was accepted by the Agency on 16th April 2019 and validated on 17th May 2019.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products, as permethrin was as of 1st May 2016, an approved active substance for product type 18 under Commission Implementing Regulation (EU) No 1090/2014.

The Agency based the evaluation on the application documents as well as the original authorisation of the Danish Environmental Protection Agency.

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal product **Loppex** on the market in Iceland, by mutual recognition of product authorisation DK-0016613-0000 issued by the Danish Environmental Protection Agency in accordance with Article 5 of Icelandic Regulation No 878/2014 on biocidal products, which implements Regulation (EU) No 528/2012 into Icelandic legislation. The Product Assessment Report is accessible under the authorisation in the R4BP3 database.

This authorisation is granted in exercise of the powers conferred by Articles 17(3), 19(1) and 34(6) of Regulation (EU) No 528/2012.

The conditions in Article 19 of Regulation (EU) No 528/2012 have been met. The authorisation is granted according to Article 22 of Regulation (EU) No 528/2012. The authorisation comes into effect on **23rd May 2019** in the following terms:

1. The composition and formulation established for the biocidal product is detailed in the Summary of the Product Characteristics in Appendices 1 and 2 – the relevant criteria for this biocidal product authorisation applies as described therein.
2. Subject to compliance with the conditions as listed in Appendix 3, the authorisation holder is authorised to place on the market the biocidal product detailed in the Summary of the Product Characteristics (Appendix 1) for the use(s) set out in that document.

3. This authorisation and associated documents outlined in the Summary of the Product Characteristics may be amended in accordance with Article 48 and 50 of Regulation (EU) No 528/2012.
4. This authorisation and associated documents outlined in the Summary of the Product Characteristics may be cancelled in the circumstances set out in Article 48 and 49 of Regulation (EU) No 528/2012.
5. Subject to paragraphs 3 and 4, this authorisation remains in force until midnight of 21st September 2028, on the condition that the active substance is registered in EU list of approved active substances.

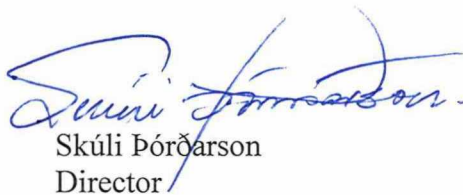
When placing the above-mentioned biocidal product on the market in Iceland, the product shall be labelled according to Article 69 of Regulation (EU) No 528/2012 and if the biocidal product is classified as hazardous according to Regulation (EU) No 1272/2008 (CLP), such labelling shall be in Icelandic (enclosed in section 6 of Appendix 1), cf. Article 4 of Regulation No 878/2014 on biocidal products.

Application for renewal of the authorisation shall be submitted at the latest 21st March 2027 according to Article 31 of Regulation (EU) No. 528/2012.

This administrative decision may be appealed before the Minister for the Environment and Natural Resources, in accordance with Article 26 of the Icelandic Administrative Act No 37/1993.

Appeals should be directed, within three months from the receipt of this decision, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland.

Sincerely



Skúli Þórðarson
Director



Hafþís Inga Ingvarsdóttir
Advisor

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Confidential Biocidal Product Characteristics

Appendix 3: Conditions of Authorisation